The opinion in support of the decision being entered today was *not* written for publication in and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte IGOR GONDA, REID M. RUBSAMEN and STEPHEN J. FARR

Appeal No. 2006-1762
Application No. 09/848,774
Technology Center 3700

ON BRIEF

Before BAHR, LEVY, and FETTING, *Administrative Patent Judges.*

FETTING, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 22 through 28, which are all of the claims pending in this application.

We AFFIRM.

BACKGROUND

The appellants' invention relates to an insulin inhaler. An understanding of the invention can be derived from a reading of exemplary claim 22, which is reproduced below.

22. A method for treating diabetes mellitus in a patient comprising the steps of:
    a. supplying a predetermined amount of dry insulin powder to an inhalation device;
    b. releasing a pressurized gas over the predetermined amount of dry insulin powder to create an aerosolized suspension comprising powder suspended in air, wherein the aerosolized suspension contains an amount of insulin that is 2-10 times higher than the amount needed to be absorbed in the bloodstream of the patient; and
    c. inhaling the aerosolized suspension at a flow rate and volume sufficient to allow the patient to absorb in the bloodstream a controlled dose of insulin that comprises between 1-50 units of insulin.

PRIOR ART

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Velasquez	5,192,548	March 9, 1993
Schenk	PCT WO 90/07351	July 12, 1990

Isselbacher et al. (ed.), Harrison's Principles of Internal Medicine, 13th Edition, Vol. 2, pp. 1986-1987, 1994 (Harrison)

REJECTION

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejection, we make reference to the examiner's answer (mailed Aug 12, 2004) for the reasoning in support of the rejection, and to appellants' brief (filed May 10, 2004) and reply brief (filed Oct 12, 2004) for the arguments thereagainst.

Claims 22 through 38 stand rejected under 35 U.S.C. § 103 as obvious over Schenk in view of Velasquez.

OPINION

In reaching our decision in this appeal, we have given careful consideration to appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by appellants and the examiner. As a consequence of our review, we make the determinations that follow.

Claims 22 through 38 rejected under 35 U.S.C. § 103 as obvious over Schenk in view of Velasquez.

As to claims 22 and 23, the appellants argue that the art fails to show the claim elements of "the aerosolized suspension contains an amount of insulin that is 2-10 times higher than the amount needed to be absorbed in the bloodstream of the patient" and "inhaling the aerosolized suspension at a flow rate and volume sufficient to allow the patient to absorb in the bloodstream a controlled dose of insulin that comprises between 1-50 units of insulin." [See Brief at p. 13]. The appellants go on to argue that the law does not recognize an "obvious to try"/ "routine experimentation" standard for proof of obviousness. [See Brief at p. 14].

The examiner responds that the claimed dose of 1-50 units is that which is administered to patients in typical administration, as evidenced by Harrison. The examiner goes on to argue that the examiner has not applied an "obvious to try" argument, but has applied the taught application of Velasquez' insulin powder to Schenk's inhaler, and that a person of ordinary skill in the art would know the standard guidelines for the number of units that are needed to be absorbed and would adjust the amount inhaled to achieve that amount accordingly. The examiner also responds that a person of ordinary skill in the art would know that the amount of aerolized suspension would have to be substantially higher than the amount needed to be absorbed and that the specification shows no criticality for the range of 2-10 times the amount. [See Answer at p. 5-8]

The appellants responded that neither reference discloses delivery to the bloodstream through inhalation let alone in controlled doses. [See Reply Brief at p. 5-6]. The appellants further argue that any guidelines that might be found in the art, including Harrison, refer to injected rather than inhaled insulin. [See Reply Brief at p. 6].

We first note that none of the claims contain limitations specifying structural characteristics that control the amount of insulin inhaled or actually absorbed. Instead, the claims recite the results to be achieved, *viz.* the amount to be inhaled and absorbed, and are consequently broad enough to embrace any technique for achieving those amounts. We further note that the ranges specified in the claims for such amounts are very broad, suggesting minimal criticality for any particular subset of such ranges.

As to the limitation regarding the number of units to be absorbed, we further note that the appellants' disclosure supports the examiner's finding that an absorption of 1-50 units would be that which a person of ordinary skill in the art would ordinarily use. [See Specification at p. 21]. This recitation confirms the findings of the examiner as to the evidentiary value of Harrison's recitation of amounts. Therefore, we find the appellants' arguments as to the limitation of an absorption of 1-50 units to be unpersuasive.

As to the limitation regarding the amount of insulin in the aerosolized suspension, we next note that with inhaled substances, it is known to a person of ordinary skill in the art that not all of the amount that is inhaled will be absorbed. The fraction that will be absorbed relative to the total amount inhaled is referred to in the art as the "respirable fraction". We note that Velasquez describes the range that such respirable fractions may embrace for the various medicaments it describes at col. 5 lines 7-15. Velasquez mentions the fraction may be in the range of 10% to 65%. Taking the inverse of this range to determine the amount of medicament that would need to be inhaled yields a range of 1.54 to 10 times the amount needed to be absorbed, which we note substantially overlaps the claimed range of 2 to 10 times. Therefore, we find the appellants' arguments as to the claim limitation of "the aerosolized suspension contains an amount of insulin that is 2- 10 times higher than the amount needed to be absorbed in the bloodstream of the patient" to be unpersuasive.

We next note that medicament that is inhaled is absorbed into the blood stream by the lungs. Therefore, we find the appellants' arguments as to the claim being toward delivery through inhalation rather than to the bloodstream to be unpersuasive.

We next note that the appellants make much of the argument that the applied art fails to show how insulin is to be inhaled in controlled delivery. However, we note that, contrary to this

argument by the appellants, both applied references describe structural devices to precisely control the amount of a medicament delivered. Velasquez resorts to precise measuring of small amounts in equal sized depressions for use in an inhaler. Schenk resorts to a metering chamber. To the extent the appellants mean to argue that neither reference teaches how to translate those structural controls into the precise amounts of insulin needed to be deposited for inhalation, we again note the broad ranges both disclosed and claimed in the appellants' application that suggest the precise amount is not critical to the invention, or more properly, the precise amount is highly dependent on the individual patient and therefore cannot be claimed with precision. Again, we note that the appellants' disclosure at p. 21 supports this high degree of variability among patients. We further note that the claim does not recite any structural mechanism for precisely matching the amounts of insulin with the patient. Therefore the appellants' arguments that neither reference teaches how to translate those structural controls into the precise amounts of insulin needed to be deposited for inhalation are unpersuasive.

We further note that the appellants have attempted to portray the examiner's rejection as an obvious to try application, followed by an admonition that the law does not support such a theory. However, our reviewing court has stated that "it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Therefore, we find the appellant's arguments as to such optimization to be unpersuasive.

As to claims 25, 26, 31 and 35, the appellants repeat the above arguments and they are equally unpersuasive as to these claims. The appellants further argue claim limitations of repetition (claim 25, 26 and 31 - [See Brief at p. 14-17]) and of lowering the glucose level to an acceptable level (claim 31 - [See Brief at p. 16]) and of controlling the glucose levels (claims 25, 26, 31 and 35 - [See Brief at p. 14-17]). We note Shenk's inhaler is inherently repeatable in operation, and that the lowering of glucose levels to an acceptable level and controlling the glucose levels are both highly dependent upon the particular patient and a person of ordinary skill in the art would monitor the patient's vital statistics to achieve the desired result in view of the high variability among patients as a matter of course. Therefore, we find the appellant's arguments to be unpersuasive.

As to the remaining claims, the appellants present no arguments to them separate from those indicated above, and therefore those claims stand or fall with claim 22.

Accordingly we sustain the examiner's rejection of claims 22 through 38 rejected under 35 U.S.C. § 103 as obvious over Schenk in view of Velasquez.

REMARKS

We note that the phrase "respirable fraction" is a term of art that may be pertinent in resolving any further patentability issues concerning the amount of a medicament needed to be inhaled to achieve appropriate absorption.

CONCLUSION

To summarize,

- The rejection of claims 22 through 38 rejected under 35 U.S.C. § 103 as obvious over Schenk in view of Velasquez is sustained.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136 (a) (1) (iv).

AFFIRMED

JENNIFER D. BAHR
Administrative Patent Judge

STUART S. LEVY
Administrative Patent Judge

ANTON W. FETTING
Administrative Patent Judge

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